Providing optimal exposure to youth with anxiety disorders: effectiveness and working mechanisms

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON45853

Source
ToetsingOnline

Brief title
TOPIC (Treatment OPtimal exposure In Clinical practice)

Condition

- Anxiety disorders and symptoms

Synonym
anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Karakter Kinder- en jeugdpsychiatrie
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: anxiety disorder, effectiveness, exposure therapy

Outcome measures

Primary outcome

The main study parameter is change in the severity of the anxiety disorder as

measured with the ADIS, a semi-structured clinical interview.

Secondary outcome

Secundary study parameters are decreases in harm expectancies and habituation

of fear and whether these predict treatment outcome.

Study description

Background summary

Although exposure based cognitive behaviour therapy (CBT) is effective in reducing anxiety in youth, there is ample room for improvement. One way to improve its effectiveness may be to incorporate findings from recent experimental research regarding underlying mechanisms into the standardised CBT treatments. While most CBT manuals are based on the assumption that *habituation*, the experience that anxiety will decrease when confronted with the feared situation, is responsible for treatment effects, findings from experimental research are in line with the *inhibitory learning hypothesis*. In this hypothesis, it is posited that a non-anxiety eliciting association is formed during CBT which exists parallel to the intact remaining anxiety eliciting association. In order for CBT to be most effective, the key is to maximally enhance the non-anxiety association by using various techniques. This newly adapted version of exposure-based CBT is referred to as *optimal exposure*.

Study objective

The goal of the study is to examine whether optimal exposure is more effective than CBT as usual in youth with anxiety disorders. The secondary objective is to investigate whether decreases in harm expectancies are predictive of treatment outcome, as predicted by the inhibitory learning hypothesis, and whether changes in anxiety during exposure are predictive of treatment outcome

as predicted by the habituation hypothesis.

Study design

The study is a multiple-baseline intervention study with children being randomly assigned to a 2-, 4-, 6- or 8-week waitlist period.

Intervention

Optimal exposure. Youth will be exposed to their fears in a step-by-step manner. Therapists use a newly adapted CBT treatment protocol and will be supervised bi-weekly.

Study burden and risks

Patients profit from participation in this study by receiving state-of-the-art treatment. At pre-treatment, posttreatment and follow-up, the semi-structured clinical interview ADIS is conducted with youth and parents. This takes 90 minutes maximally. At pre-treatment youth and parents are asked to fill in a questionnaire which takes 20 minutes. Youth and parents are asked to fill in questionnaires twice a week during the study (22 weeks in total). Filling in the questionnaire takes five minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

* Age between 12-18
* Sufficient knowledge of the Dutch language
* A primary diagnosis of at least one of the following anxiety disorders: separation anxiety, generalized anxiety disorder, or social phobia according to the ADIS

Exclusion criteria

* Absence of permission of legal guardian(s)
* Different and more urgent request for help
* (Risk of) suicidality, psychosis or domestic violence
* Mental retardation
* Use of medication for psychiatric problems

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65797.091.18